

The Department of Health and Human Services
Meeting of the
Secretary's Advisory Committee on Human Research Protections (SACHRP)
Thursday, October 3, 2013 – Friday, October 4, 2013
Hubert H. Humphrey Building, Room 800
AGENDA

Thursday, October 3, 2013

8:30 a.m. – 8:45 a.m.

Welcome: Opening Remarks

Jeffrey R. Botkin, M.D.
SACHRP Chair

Jerry Menikoff, M.D., J.D.
Director, OHRP

8:45 a.m.- 9:15 a.m.

Welcome and Remarks

Howard Koh, M.D., M.P.H.
Assistant Secretary for Health
U.S. Department of Health and Human Services

9:15 a.m.- 10:15 a.m.

Subcommittee on Harmonization (SOH)

David Forster, J.D., M.A., C.I.P., SOH Co-chair
Mark Barnes, J.D., SOH Co-chair

10:15 a.m.- 10:30 a.m.

BREAK

10:30 a.m. – 12:00 p.m.

Clustered Randomized Trials and Informed Consent

David Forster, J.D., M.A., C.I.P., SOH Co-chair

12:00 p.m. – 1:00 p.m.

LUNCH

1:00 p.m. – 4:30 p.m.

**A Discussion of Cluster Randomization, Risk
Assessment and Consent Requirements**

1:00 p.m.- 2:30 p.m.

*Population Effect of Universal Testing and Immediate ART
to Reduce HIV Transmission, HPTN 071. PoPART*
Mark Barnes, J.D., SOH Co-chair

2:30 p.m. - 4:30 p.m.

NIH Collaboratory Trials
Jerry Menikoff, M.D., J.D.
Director, OHRP

4:30 p.m. – 4:45 p.m.

SACHRP Next Steps

4:45 p.m. – 5:00 p.m.

Public Comment

5:00 p.m. – 5:15 p.m.

Wrap-up Discussion and Adjourn

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Opening Remarks

Jeffrey Botkin, M.D.
SACHRP Chair

Jerry Menikoff, M.D., J.D.,
Director, OHRP

8:45 a.m.- 10:30 a.m.

Subpart A Subcommittee (SAS)

Re-envisioning Engagement

Daniel K. Nelson, M.S., CIP, SAS Co-chair
David Borasky, M.P.H., CIP, SAS Co-chair

10:30 a.m. – 11:00 a.m.

BREAK

11:00 a.m.- 12:15 p.m.

Subpart A Subcommittee (SAS)

Continued

12:15 p.m.- 1:15 p.m.

LUNCH

1:15 p.m. – 3:00 p.m.

Subpart A Subcommittee (SAS)

Continued

3:00 p.m.- 4:00 p.m.

Certificates of Confidentiality

David Forster, J.D., M.A., C.I.P., SOH Co-chair

4:00 p.m.- 4:15 p.m.

Public Comment

4:15 p.m. – 4:30 p.m.

Wrap-up Discussion and Adjourn